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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/718,770	11/22/2000	R. Terry Dunlay	97, 022-F3	5398

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EXAMINER

MARSCHER, ARDIN H

ART UNIT PAPER NUMBER

1631

DATE MAILED: 09/30/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 09/718,770	<b>Applicant(s)</b> DUNLAY ET AL.	
	<b>Examiner</b> Ardin Marschel	<b>Art Unit</b> 1631	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 13-25 is/are pending in the application.  
     4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 13-25 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
     a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____.  |

## **DETAILED ACTION**

### **TITLE**

The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed. The pending claims are directed to a method on a computer system directed to screening cell data from a plate containing wells. The present title lacks any of these specificities and is vastly more generic than the actually claimed subject matter and thus not specifically representative thereof.

### **NEW MATTER**

Claims 13-25 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

NEW MATTER has been added via certain limitations in the newly presented claims. Figure 7 was cited in REMARKS, filed 5/18/01, as part of the support for the new claims. It is noted that item 100 in Figure 7 cites operator input of necessary parameters. This is different from what apparently corresponds in claim 13 as part b). Said Figure 7 lacks any storing...in a database limitation as now in said part b). Figure 7 indicates that an operator inputs the data but this operator concept is not cited in said part b). Also, said part b) of claim 13 specifies that the parameters are used for

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screening of the plate, but no such specificity is present in Figure 7. Additionally, the bottom of Figure 7 indicates the generation of a Report on plate but does not indicate any "summary" therein as now set forth in claim 13, part c), subpart viii). Consideration of the other citations pointed to by applicants in said REMARKS have not revealed further written support for the apparent NEW MATTER described above in claim 13.

NEW MATTER has also been added via claims 23-25 regarding various limitations therein. For example, applicants pointed to page 9, lines 12-18, for written support of claim 23. Consideration of said page 9 citation reveals that "different fluorescent agents" is cited therein whereas claim 23 broadens this to "fluorescent agents" which is NEW MATTER. Page 11, line 22, through page 12, line 19, was cited in said REMARKS to support claims 24 and 25. Consideration of the fluorescence disclosures on said pages 11-12 reveals that ratios of fluorescent intensities are only disclosed regarding comparison of the cytoplasmic mask to average fluorescent intensity within the cell nucleus. In claims 24 and 25 NEW MATTER has been added by broadening the ratio of fluorescent intensity limitation without further limitation regarding cytoplasmic mask or an average of cell nucleus fluorescent intensity.

### **VAGUENESS AND INDEFINITENESS**

Claims 13-25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In the preamble of claim 13, lines 1-2, the method is directed to "cell" screening data, however, confusingly, no cell limitation(s) are set forth in the actual claim steps.

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Also, said preamble sets forth the method as being directed to "retrieval" of cell screening data, however, confusingly, no "retrieval" limitation(s) are set forth in the actual claim steps. Additionally, said preamble sets forth the method as being "on a computer system", however, confusingly, no "computer system" is cited in the actual claim steps. Thus, the claim is vague and indefinite as to whether the preamble citations as noted above control the metes and bounds of the claim practice or whether the actual method steps in parts a) – c) control the metes and bounds. Clarification via clearer claim wording is requested. Claims 14-25 also contain these unclarities due to their dependence directly or indirectly from claim 13.

#### **PRIOR ART**

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 13-25 are rejected under 35 U.S.C. 102(e)(2) as being clearly anticipated by Sabry et al. (P/N 6,615,141).

Sabry et al. depicts a plate with wells therein being scanned in Figures 4 and 5. Cellular information knowledge is acquired as summarized in the abstract of Sabry et al. including the storing of such information in a database with descriptors and features etc. Thus, Sabry et al. discloses an invention as is instantly claimed regarding subject matter

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area. In column 2, lines 42-49, the system of the reference utilizes computer codes etc. for storing and retrieving cellular and substance information. Specific cellular information such as image and feature data that is captured in the imaging system of the reference are listed in column 6, lines 47-66, and stored in the database as also limitations in instant claims 23-25 as well as in claim 13, part c), subparts i) – v). Input data relating to a test compound are described in column 13, line 50, through column 14, line 22, as also required in instant claims 13, step b), and 15. The provided plate (instant claim 13, step a)) imaging of the reference includes the well by well selective and repetitive steps as in instant claim 13, step c), as described in column 10, lines 37-51, via X-Y control directed to each well on the plate. The well by well data acquisition as well as whole plate data acquisition and summaries as files as in instant claim 13, step c), substeps vi) – ix), is disclosed in the reference in column 16, line 15, through column 18, line 14, and more specifically in column 16, lines 50-56. Calculations on data summaries such as in instant claim 13, part c), subparts vi) and viii) are set forth in the reference in column 14, line 23, through column 16, line 15, which includes both cellular image data for cell samples in wells as well as comparative calculations that must include multiple samples and well data in a plate summary in order to result in data clustering, statistical analysis, heuristic classification, phylogenetic trees etc. Thus, the disclosure of the multiple aspects of the imaging methodology of Sabry et al. anticipates the multiple aspects of the instantly claimed invention.

#### **INFORMATION DISCLOSURE STATEMENT**

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Applicants have stated that a PTO Form 1449 has been supplied with the IDS, filed 12/13/01. Confusingly, no such PTO Form 1449 has been found in the record of the instant application. Applicants are requested to supply a copy for initialing as appropriate.

No claim is allowed.

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the Central PTO Fax Center. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993)(See 37 CFR § 1.6(d)). The Central PTO Fax Center number is (703) 872-9306.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ardin Marschel, Ph.D., whose telephone number is (571) 272-0718. The examiner can normally be reached on Monday-Friday from 8 A.M. to 4 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, Ph.D., can be reached on (571) 272-0722.

Any inquiry of a general nature or relating to the status of this application should be directed to Legal Instrument Examiner, Tina Plunkett, whose telephone number is (571) 272-0549.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

September 27, 2004

*Ardin H. Marschel* 9/27/04  
ARDIN H. MARSCHEL  
PRIMARY EXAMINER